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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,381	06/13/2005	Andrew Kaplan	5470-374	2353

20792 7590 10/01/2007
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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
10/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,381	KAPLAN ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,20,36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17,20,36 and 37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the preliminary amendment filed on 18 January 2005. Claims 18, 19 and 21-35 have been cancelled. Claims 1-17, 20, 36 and 37 are pending and restricted.

Election/Restrictions

Restriction is required under 35 U.S.C. §121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-17, drawn to a method of identifying an inhibitor of retrovirus protease activity.

Group II, claim 20, drawn to a kit comprising a nucleic acid and a substrate.

Group III, claims 21 and 22, drawn to a nucleic acid that encodes a retrovirus GagPol or a fragment thereof; and a vector comprising the nucleic acid.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As set forth above, each Group requires a technical feature that is not required by any of the other groups.

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The technical feature of Group I lacks an inventive step as the combination of Block patent (5,532,124; 2 July 1996) and Hui patent (6,001,810; 14 December 1999) disclose the method of identifying a retroviral protease inhibitor.

The Block patent (US 5,532,124) teaches the discovery of HIV protease inhibitors. Each candidate inhibitor must be tested for its ability to prevent HIV protease from enzymatically cleaving substrates such as preparations of either Gag-Pol precursors or

synthetic oligopeptides containing the HIV protease recognition sequence. See column 2, line 4-17. The method of identifying a medically important target, such as an HIV protease inhibitor, comprises providing a microorganism, such as a bacteria or yeast; expressing both the target protein (HIV protease) and a modified reporter function such that the reporter function may be deactivated by the protease; adding a test compound to the culture medium containing the microorganism; and observing the growth or color change of the organism in the culture medium. Growth or color change of the organism indicates that the test compound may be a medically important agent. See column 7, line 17-38. Cellular proteases do not cleave the Pr55 gag and Pr160 Gag-Pol polyproteins. HIV protease cleaves at the Tyr-Pro peptide bond and recombinant protease produced in *E. coli* is functional and can *in vitro* cleave the heptapeptide Ser-Gln-Asn-Tyr-Pro-Ile-Val (protease cleavage recognition sequence) inserted into a Tet protein. See column 8, line 10-65.

The Hui patent (US 6,001,810) teaches methods for the discovery of HIV-1 protease inhibitors based upon the high level expression of the HIV-1 *gag* and *pol* genes in Escherichia coli (Abstract, Col. 1, line 10-42). The protease assay involves cloning and expressing genes encoding the HIV-1 Pol fragment containing the mature protease and the Gag precursor, preparing the protease and Gag proteins, then setting up proteolytic cleavage reactions in which the Gag proteins are added as substrates for the proteases that are pre-incubated with the an inhibitory candidate compound. The reactions were then electrophoresed and blotted onto nitrocellulose filters. Monoclonal antibodies that recognize epitopes on p24 and p17 viral proteins (which can serve as the tether or detectable moiety) were contacted with the filter then visualized using standard biotinylation or radionuclear techniques. Compounds that prevented the maturation of the Gag polypeptide into mature viral proteins p24 and p17 were then ranked according to their HIV-1 protease inhibitory activity. See column 7, line 31 to column 8, line 33.

Since the claimed invention is known in the art, it does not make a contribution over the prior art, therefore unity is lacking.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The nucleic acid species of the first genus are as follows:

1. a nucleic acid that encodes a retrovirus GagPol or a fragment thereof comprising a protease, a protease cleavage site, a tether and a detectable moiety;

2. a nucleic acid that encodes a retrovirus GagPol or a fragment thereof comprising the retrovirus protease and transframe protein;

3. a nucleic acid that encodes a retrovirus GagPol or a fragment thereof comprising the retrovirus protease and the retrovirus reverse transcriptase; and

4. a nucleic acid that encodes a retrovirus GagPol.

The detectable moiety species of the second genus are as follows:

a. luciferase;

b. hemagglutinin antigen;

c. maltose binding protein;

d. c-myc;

e. FLAG epitope;

f. glutathione-S transferase;

g. fluorescent moiety;

h. β-glucuronidase;

i. alkaline phosphatase; and

j. β-galactosidase; and

k. an epitope within the retroviru GagPol or fragment thereof.

Applicant is required, in reply to this action, to elect, from each genus, a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The first genus – species 1 – claim 1;
The first genus – species 2 – claims 4-8;
The first genus – species 3 – claims 9-10;
The first genus – species 4 – claim 11;

The second genus – species a-j – claim 15;
The second genus – species k – claim 16;

The following claim(s) are generic: 1-3 and 17.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the same reasons as set forth above. The nucleic acid species and the protein species do not share a common structure, property or activity. The sequence of one species does not require the sequence of another species. Therefore, the species lack the same special technical feature.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Applicant is advised that the final rules on claims and continuations were published in the Federal Register Tuesday, August 21, 2007. As of November 1, 2007, the claims in each application may not exceed 5 independent claims or 25 total claims absent the applicant assisting the examination process through the filing of an Examination Support Document (ESD). The following is taken from the published rules package:

- **Applicants may present, without an ESD, up to:**
    - **Five (5) independent claims or**
    - **Twenty-five (25) total claims in an application.**
- **Applicant may present more than 5/25 claims, if applicant files an ESD before the first Office action on the merits (FAOM).**
- **The 5/25 claim threshold does not count withdrawn claims.**
    - **Applicant may provide a suggested restriction requirement (SRR) before first Office action or a restriction requirement.**
- **The 5/25 claim threshold does count all of the claims present in other copending application(s) having a patentably indistinct claim, but not the claims in issued patents.**
    - **Applicant may present up to 15/75 claims via an initial application and 2 continuation or CIP applications prosecuted serially.**

The final rules will become effective November 1, 2007, and will apply to all pending applications as of that date. Applicants are advised to ensure that the elected claims are compliant with the new rules to avoid delay of prosecution. There will be no change to the examiner practice prior to the date the rules become effective. Information on the new rules will be available at:

http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html

If Applicant has any questions concerning the new rules, email patentpractice@uspto.gov or call 571-272-7704.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Thu, 9:00 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Louise Humphrey, Ph.D.
Assistant Patent Examiner
15 September 2007

Jeffrey Parkin, Ph.D.
Primary Patent Examiner